In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 99-540V
March 26, 2007

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NICOLETTE DAVIS,	*	
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Petitioner,	*	
	*	
v.	*	Hepatitis B vaccine; MS
	*	five and six years later;
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	ankylosing spondylitis
	*	
Respondent.	*	
* *		

ORDER TO SHOW CAUSE[1]

Petitioner filed a petition on July 29, 1999, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., under the name of Karen Davis (the undersigned issued an

[1] Because this order contains a reasoned explanation for the special master's action in this case, the special master intends to post this order on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

Order on November 17, 2006 granting petitioner's motion to amend the caption), alleging that she received hepatitis B vaccine on August 23, 1993 and experienced an adverse reaction.

Petitioner filed her affidavit, stating she received hepatitis B vaccine on August 12, 1993. P. Ex. 1, p. 1. She alleges that within 12 hours of receiving the vaccine, she had a fever of 101° which lasted five to six days, and shaking chills. She alleges she developed severe headache, severe neck ache, severe joint and muscle pain, mild abdominal pain, and weakness for several weeks. P. Ex. 1, p. 2.

She alleges within hours after she received the second hepatitis B vaccine on September 30, 1993 that she developed the same symptoms, but more severe. The fever of 101° lasted two weeks, she developed daily diarrhea, and she had left arm and leg weakness and severe joint aches. *Id.*

Petitioner alleges after she received the third hepatitis B vaccination on March 9, 1994, which caused a fever of 102°-103°, that her hair started to fall out in clumps two or three weeks later, and developed severe headaches and blurred vision. *Id.* She was depressed, confused, had lost her short-term memory, lost 15 pounds, and had tingling in her left arm and leg. *Id.* at pp. 2-3. She could not sleep at night and became exhausted. She vomited constantly. She applied for disability in November 1997. She had tachycardia, and surgery in 1999 to correct this. *Id.* at p. 3. She was diagnosed with reactive arthritis and multiple sclerosis. *Id.*

FACTS

Petitioner was born on August 3, 1960.

Petitioner received the first hepatitis B vaccination on August 12, 1993. P. Ex. 28.

Her first visit to a doctor after vaccination was on September 10, 1993, when she saw Dr. Robert Nold, complaining of discharge from her left nipple and a spot on her abdomen that itched. She also wanted a pap test while she was there. She gave a history of being allergic to codeine. Med. recs. at Ex. 2, p. 7. There is no other medical record on file between the first and second hepatitis B vaccinations.

Petitioner received the second hepatitis B vaccination on September 30, 1993. P. Ex. 28. There is no medical record on file of a visit to a doctor during the five months and one week between the second and third hepatitis B vaccinations.

Petitioner received the third hepatitis B vaccination on March 9, 1994. P. Ex. 28.

Two and one-half months later, on May 20, 1994, petitioner saw Dr. Nold, complaining of pain in the right side of her neck under her ear which felt swollen with ear pops. She had had this before since February 1993, 15 months earlier (which was six months before the first hepatitis B vaccination). Petitioner never mentioned any other symptom. Med. recs. at Ex. 2, p. 9.

Three months later, on August 30, 1994, petitioner had an upper gastrointestinal series, which was unremarkable. Med. recs. at Ex. 3, p. 2. On that same date, she had a gallbladder ultrasound which was normal. Med. recs. at Ex. 3, p. 3.

Five months and one week later, on March 10, 1995, petitioner saw Dr. Nold, complaining of intermittent pain in her left leg. Med. recs. at Ex. 2, p. 14. This was one year after the third hepatitis B vaccination.

Ten and one-half months later, on January 25, 1996, petitioner had an echocardiogram done because of a racing heart and dizziness. Med. recs. at Ex. 2, p. 23. She had mild prolapse of the anterior leaflet of the mitral valve. Otherwise, she was normal. *Id.*

Four and one-half months later, on June 10, 1996, petitioner saw Dr. Nold, complaining of stress, not sleeping well, and diarrhea for six weeks. Med. recs. at Ex. 2, p. 28. This was two years and three months after the third hepatitis B vaccination.

On June 24, 1996, petitioner saw Dr. Nold, complaining of a temperature, low back pain, and fatigue. Med. recs. at Ex. 2, p. 31. She gave a five-day history of temperature to 100° nightly, back pain, mild dysuria, and frequency. She had a history of cystitis in the distant past. She was very concerned about the risk of hypertension with multiple illnesses. She had significant exposure as a federal law enforcement officer (doing raids on crack houses, with direct blood exposures to ungloved hands on multiple occasions), as well as donor sperm used in artificial insemination and a blood transfusion during a Caesarean section in 1990. *Id.* She was diagnosed with an early urinary tract infection. *Id.* It was questionable whether petitioner had HIV and blood was taken to see if she had a subacute bacterial endocarditis (SBE). Petitioner was given pretest HIV counseling on negative and false negative results and positive and false positive results. *Id.* Petitioner understood and her written consent was in the chart. *Id.*

On July 12, 1996, Elizabeth Senn, a psychotherapist, wrote a letter to petitioner's supervisor that she experienced illness due to work-related stress and would be out of the office from July 15-19, 1996. Med. recs. at Ex. 7, p. 1.

On August 5, 1996, Elizabeth Senn wrote a letter to petitioner's supervisor that petitioner experienced illness due to work-related stress and would be out of the office from August 5-9, 1996. Med. recs. at Ex. 7, p. 2.

On August 9, 1996, petitioner saw Dr. Nold, complaining of severe intermittent diarrhea with stomach pain, a lot of belching, and burning. She had a lot of stress at work. Med. recs. at Ex. 2, p. 32.

On September 4, 1996, petitioner saw Dr. Nold, complaining of bronchial congestion and a history of allergies. Med. recs. at Ex. 2, p. 33. She had yellow/green production for a few days. *Id.* On examination, her right tympanic membrane was erythematous. She had right central cervical adenopathy. She was diagnosed with bronchitis and early right otitis media. *Id.*

On September 24, 1996, petitioner returned to Dr. Nold, complaining of intermittent diarrhea and vomiting, and right earache. Med. recs. at Ex. 2, p. 34. She was diagnosed with a stress-induced problem with nausea and vomiting. *Id.* Dr. Nold wrote a note dated September 24, 1996 that petitioner was to be off work for two weeks. Med. recs. at Ex. 2, p. 35.

On September 30, 1996, Dr. Robert Nold wrote a "To Whom It May Concern" letter, stating that petitioner had been in his office numerous times in September with nausea, vomiting, and diarrhea. She was also having nightmares and, thus, less restful sleep. Dr. Nold's diagnosis was that all these symptoms were stress-related, secondary to petitioner's work situation. She was advised to remain off work until this situation had resolved. She was on Librax, Paxil, Valium, and Zantac. Med. recs. at Ex. 2, p. 36.

On November 11, 1996, Dr. Beryl W. Langley, a psychiatrist, wrote a "To Whom It May Concern" letter. Med. recs. at Ex. 2, p. 67. Dr. Langley first saw petitioner on October 10, 1996

with subsequent visits on October 14, 1996 and November 11, 1996. Her therapist, Elizabeth Senn, who had been seeing petitioner since May 1996, referred petitioner. Petitioner was on psychiatric medications which Dr. Nold prescribed: Paxil 20 mg. daily, which Dr. Langley recommended increasing to 30 mg., Desyrel 50 mg., and Valium 10 mg. occasionally when petitioner was under excessive stress. *Id.*

Petitioner described her problems as tearfulness, anxiety, and difficulty concentrating with frequent severe nightmares and occasional flashbacks. She also described significant gastrointestinal dysfunction, including frequent diarrhea and loss of appetite. Petitioner ascribed her symptoms to a stressful work environment, particularly during the prior two years (which would mean the stressful work began in 1994). A number of incidents had occurred during that time, including the most serious which was sexual harassment by a federal marshal on October 26, 1995. *Id.*

On further evaluation, it appeared that petitioner's problems started seven years previously (which would mean in 1989) when she attended the U.S. Marshal Academy. She had been in other branches of law enforcement previously without any difficulties. At the academy, there were few women and there were frequent comments and physically intimidating events which were traumatic to her. She still experienced some of these episodes in flashbacks. After graduating from the academy, she worked in Florida in the U.S. Marshal's office and had no significant problems there except for one supervisor who made a subtle attempt to institute a sexual relationship with her, which she dealt with verbally. *Id.*

When petitioner was transferred to Louisville, she experienced no particular difficulties until early 1994 when the chief told her that he was leaving the office. He had begun to treat her

with less respect and she was aware her assignments were less favorable than they had been. In February 1994, despite her statements that the weather was hazardous, she was ignored and she and her partner were sent out on assignment which resulted in a traffic accident, with her car underneath a semi. Petitioner began to have anxiety and nightmares at that time. Med. recs. at Ex. 2, p. 68.

When petitioner's supervisor left, his replacement was the same individual who had propositioned her in Miami. Petitioner had previously reported on this individual and, when he took over the office in Louisville, her treatment deteriorated further until the supervisor sexually assaulted her on October 26, 1995 in front of a deputy. Petitioner had anxiety and nightmares again and became much more depressed. In August 1996, this supervisor hit her on the rear with a rolled up newspaper. She again complained to a superior. *Id.*

Currently, petitioner had significant difficulty maintaining her equilibrium. She felt very uncomfortable in her work environment, which became much more hostile especially since the case resulted in litigation. She had frequent nightmares including situations where the supervisor was threatening her life with weapons or she was dying. She frequently woke from these nightmares in an agitated state. She also had increased diarrhea and difficulty swallowing. She lost a lot of weight. She was more withdrawn and had lost interest in her activities. *Id.*

Dr. Langley diagnosed petitioner with post-traumatic stress disorder directly related to the stress of her job with the U.S. Marshal's office and the specific incidents. Dr. Langley did not think petitioner should be working since the work stress was making her significantly worse. *Id.*

On December 6, 1996, petitioner went to Dr. Nold, complaining of intermittent pain under her right anterior ribs since October which had worsened in the prior two days. Med. recs.

at Ex. 2, p. 37. Dr. Nold noted pain in the right upper quadrant for three months which had become constant, occasionally grabbing and sharp, which was unassociated with eating. He diagnosed probable cholecystic pain. *Id.*

On December 9, 1996, petitioner had an ultrasound of her upper abdomen because of nausea and pain. It was unremarkable. Med. recs. at Ex. 3, p. 4.

On December 13, 1996, petitioner returned to Dr. Nold with continuing stomach pains on the right side. Med. recs. at Ex. 2, p. 38.

On February 12, 1997, petitioner saw Dr. Nold, complaining of shortness of air, cough, and head congestion. She was taking Amoxillin, and had sinus drainage. Med. recs. at Ex. 2, p. 39. Dr. Nold also prescribed Robitussin. *Id.*

On February 22, 1997, petitioner returned to Dr. Nold, complaining of bronchial congestion, hoarseness, cough, a lot of sinus drainage, and congestion. Med. recs. at Ex. 2, p. 40. She had constant green sputum. She had improved for four days on Solumedial. Now she was back with colored drainage. She was diagnosed with bronchitis and sinusitis. She was prescribed Keflex and Prednisone taper. *Id.*

On February 26, 1997, petitioner saw Dr. Nold for a recheck. She was no better. Med. recs. at Ex. 2, p. 41.

On March 20, 1997, petitioner had a CT scan done of her sinuses at Columbia Audubon Hospital because of headache and neck pain. Her sinuses were clear. Med. recs. at Ex. 3, p. 5.

On March 20, 1997, petitioner had a CT scan done of her brain at Columbia Audubon Hospital because of headache and neck pain. The CT was unremarkable. Med. recs. at Ex. 3, p. 6.

On March 24, 1997, petitioner had an MRI done of her brain at Columbia Audubon Hospital because of headaches. The MRI was unremarkable. Med. recs. at Ex. 3, p. 12. She did not have any evidence of demyelinating or ischemic disease. *Id.*

On March 24, 1997, petitioner had an EEG done at Columbia Audubon Hospital because of headaches. The EEG was normal. Med. recs. at Ex. 3, p. 14.

On March 24, 1997, petitioner had an MRI done of her cervical spine because of left arm and leg pain. The MRI was negative. Med. recs. at Ex. 3, p. 15.

On April 26, 1997, petitioner saw Dr. Nold with uncontrollable diarrhea and a clot in her hand which was not going away. This was from an IV site. The diarrhea had been going on for three days with occasional vomiting. She was diagnosed with gastroenteritis. Med. recs. at Ex. 2, p. 48.

On May 14, 1997, petitioner went to Dr. Nold, complaining of back pain for two weeks. She was going to physical therapy. The pain radiated into the shoulders. She had chronic fatigue. She had severe muscle strain for two weeks in the left upper back and shoulder. She was very depressed and frustrated that she was getting worse and not better. In general, she was getting worse over the past year and was very tearful. She was diagnosed with muscle spasm and prescribed Valium. She refused other anti-depressant treatment. Med. recs. at Ex. 2, p. 49.

On May 20, 1997, petitioner had a thoracic spine x-ray because of back and shoulder pain. She had mild scoliosis, but no acute or destructive lesion. Med. recs. at Ex. 3, p. 19.

On May 21, 1997, petitioner's husband called Dr. Nold's office saying that petitioner was having back problems that had gone up to her neck. Med. recs. at Ex. 2, p. 52.

On May 28, 1997, petitioner returned to Dr. Langley, the psychiatrist. Med. recs. at Ex. 2, p. 70. Petitioner's clinical condition appeared to have deteriorated because of severe muscle spasms which kept her immobile. Med. recs. at Ex. 2, p. 71. Her diagnosis was post-traumatic stress disorder with psychosomatic symptoms. Dr. Langley thought petitioner would require another 12 months before being stable enough to handle the stresses of her workplace. She lost a great deal of weight and in view of her anxiety and depression as well as these psychosomatic symptoms, she was completely unable to function in the workplace, especially as a federal marshal. She also had difficulty functioning at home and her relationship with her husband and daughter deteriorated because of her extreme stress. *Id.*

On June 6, 1997, petitioner saw Dr. Nold with back pain between her shoulder blades. The physical therapist told her she had a pinched nerve or muscle. The pain was constant and severe. She had intermittent fever and chills at night, and fatigue. Med. recs. at Ex. 2, p. 56.

On June 9, 1997, petitioner called Dr. Nold's office and said that she woke up with her knees numb and joint pain in her hips. Med. recs. at Ex. 2, p. 59.

On June 12, 1997, petitioner had an MRI of her thoracic spine because of back pain and leg numbness, as well as pain between the shoulder blades. Med. recs. at Ex. 3, p. 20. She had degenerative disk disease with small disk herniations somewhat greater on the right at T8-9 and greater on the left at T10-11. *Id.*

On June 23, 1997, petitioner saw Dr. Nold, complaining of insomnia, electric shocks through her body, itchy skin, fatigue, and radiating pain in her back. Med. recs. at Ex. 2, p. 62.

On June 23, 1997, Dr. Nold wrote a "To Whom It May Concern" letter. He stated he had been petitioner's primary care physician for the prior several years. She had an unremarkable

medical and surgical history. About 18 months previously (which would be about late December 1995), petitioner began to complain of insomnia, chronic fatigue, and a variety of gastrointestinal ailments, such as nausea, vomiting, and diarrhea, which Dr. Nold diagnosed as irritable bowel syndrome. Med. recs. at Ex. 2, p. 63.

During the winter season of 1995-96, petitioner had bronchitis more than once and told Dr. Nold that she was under severe work-related stress. By spring 1996, petitioner was still feeling ill and was showing "florid symptoms of depression." *Id.* She told Dr. Nold that the U.S. Marshals Service Employee Assistance Program had arranged for her to have weekly therapy sessions with a local psychotherapist Betty Senn to attempt to help petitioner deal with her work-related stress issues. *Id.*

By the end of June 1996, petitioner was fatigued, experiencing night sweats, and fevers of unknown origin, and became so alarmed that she came to his office to ask to be tested for HIV, which proved negative. During the summer and early fall of 1996, petitioner had to take about five weeks of sick leave because of nausea, vomiting, diarrhea, fever, and frequent nightmares concerning her work situation, added to her chronic sleep problem. *Id.*

In October 1996, after five months of psychotherapy with only moderate improvement, she and her psychotherapist became concerned enough to have her referred to a local psychiatrist, Dr. Beryl Langley, for evaluation. As had psychotherapist Betty Senn, Dr. Langley diagnosed petitioner with primary post-traumatic stress disorder and secondary depression. Petitioner was placed on administrative leave in November 1996. *Id.*

Petitioner did not improve notably, and in the winter of 1996-97, she had numerous episodes of bronchitis that required multiple rounds of antibiotics and two steroid injections.

Med. recs. at Ex. 2, p. 64. While the nausea, vomiting, and diarrhea were intermittent, petitioner reported that the chronic fatigue and insomnia were constant. She then reported aching in her back and neck. In March 1997, petitioner made an emergency room visit for acute cephalgia,[2] neck and back pain. She had a lumbar puncture, CT scan of the sinuses and brain, all of which were unremarkable. She was given pain medication and muscle relaxers and sent home with a diagnosis of migraine headache. *Id.*

Petitioner did not improve. Three days later, she was again in the emergency room with the same symptoms and extreme pain. She was subsequently admitted and, in the next four days, she had an EEG, MRI of the cervical spine and brain, all of which were within normal limits. She was treated with Toradol and Demerol for pain, Phenergan for nausea, and Flexeril, a muscle relaxant. Her primary diagnosis was muscle tension headache with a secondary diagnosis of depressive disorder, not elsewhere classified. *Id.*

Although petitioner's acute pain eased during the hospital stay, the muscle tension and aching remained. In early April 1997, petitioner began outpatient physical therapy three times a week, which she continued until May 9, 1997. She had some improvement in the muscular aches, although she still reported chronic fatigue, nausea, diarrhea, numbness and tingling in the left arm and leg. She then reported she felt as if she were in a fog, having trouble concentrating while driving, and had run through red lights. *Id.*

Petitioner reported that, while in outpatient physical therapy, she had muscle spasms in her left arm and shoulder. Around the end of April 1997, she developed a sharp pain between

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[2] Cephalgia is a "headache." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 333.

her shoulder blades as well as shortness of breath. She came to Dr. Nold's office in such severe pain that she was given a pain shot. Within one week, petitioner's husband had to take her back to the emergency room because of back and neck pain so severe that she could not stand unassisted. She was admitted overnight, given Demerol which eased the pain, and Flexeril. She was released with a prescription for Mepergan, a strong pain medication. *Id.*

In late May 1997, petitioner had an x-ray series of the spine done and no cause for her pain was readily identified. By early June 1997, petitioner reported that the pain was constant and she could not sleep at all even with pain and sleep medication. She reported that the muscle relaxers appeared to be doing very little good. Dr. Nold prescribed a narcotic pain medication, Oxycontin, 20 mg. dosage, as well as Soma, a muscle relaxant petitioner had not taken. *Id.*

Petitioner called Dr. Nold's office and reported that the Oxycontin just took the edge off the pain. Med. recs. at Ex. 2, p. 65. An MRI of the thoracic spine where she reported the most acute pain showed degenerative disk disease with small disk herniations at T8-9 and T10-11. Blood work drawn on June 6, 1997 showed polyclonal increase in gamma globulins, sed rate up to 42, Epstein Barr virus profile with VCA-IgG increased, EBA-NA, IgG increased. *Id.*

On June 16, 1997, petitioner returned to Dr. Nold with severe neck and back pain. She was extremely tender at several trigger point areas in the neck, back, and hip regions. Dr. Nold diagnosed fibromyalgia. Med. recs. at Ex. 2, p. 65. Dr. Nold referred petitioner to a physical medicine rehabilitative specialist, and she would be undergoing physical therapy and started on different medications to ease her pain. She was significantly depressed and fatigued. Dr. Nold saw major decline in petitioner's mental and physical health in the last 18 months, and in light of her fibromyalgia syndrome and work-related post-traumatic stress syndrome and depression, he

recommended she be granted disability because the anxiety related to her work situation could only cause greater stress, and that she be allowed to transition to a different area because she had no family there and was worried about being unable to care for her daughter. *Id.*

From June 23-28, 1997, petitioner was admitted to Jewish Hospital for back pain. On June 24, 1997, Dr. Yong K. Liu did a consultation at the request of Dr. Christopher Pitcock. Med. recs. at Ex. 8, p. 6. Petitioner said she had been in good health until March 1997 when she developed pain over the back of her neck, radiating down to the interscapular region. She was found to have leukopenia[3] according to petitioner. Severe pain from a muscle spasm in April during a physical therapy session has radiated to the substernal region and persisted despite Oxycontin. Petitioner stated that, during the last two months, her appetite decreased associated with an uncertain amount of weight loss and she had occasional fever, dizziness, and substernal pain as well as shortness of breath, but no persistent cough, night sweats, abdominal pain, recurrent nausea, vomiting, diarrhea, headache, visual disturbances or arthralgia. Petitioner was 5'8" tall and weighed 136 pounds. *Id.* She moved her arms and legs normally without swelling or tenderness. Dr. Liu's impression was history of leukopenia although, at present, she had normal blood cell counts and morphology; severe intrascapular pain of uncertain etiology and pathogenesis; a history of mitral valve prolapse; and a history of skin cancer. Med. recs. at Ex. 8, p. 7.

On June 24, 1997, petitioner had a CT scan of her lumbar spine which was negative. Med. recs. at Ex. 8, p. 4.

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[3] Leukopenia is a "reduction in the number of leukocytes in the blood below about 5000 per cu. mm." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1022.

On June 26, 1997, petitioner had an MRI of her cervical spine. The impression was mild degenerative disk disease at C3-4, C4-5, and C5-6. Med. recs. at Ex. 8, p. 11.

On June 26, 1997, petitioner had an MRI of her brain. She had occasional non-specific punctate areas of increased T2 signal in the deep periventricular white matter. These were very non-specific and of very questionable significance. Med. recs. at Ex. 8, p. 12.

On August 13, 1997, petitioner went to the Cooper Clinic and saw Dr. Marilyn I. Barr, having moved from Louisville, KY, to Fort Smith, Arkansas. Med. recs. at Ex. 9, p. 1. She stated she was in good health until she was sexually assaulted by another marshal at her work place. She had been under a lot of stress and strain because of her job. She now came with the diagnoses of fibromyalgia, chronic fatigue syndrome, severe back pain, degenerative disk disease, herniated disk, and mitral valve prolapse. She stated all this happened since the assault. She was on Paxil 20 mg. daily, Xanax 0.5 three times a day, Lodine 800 mg. daily, and Traxodone 75 mg. Since her move, she was on Paxil and Xanax. She stated she had frequent numbness in her left arm and leg for which no one had discovered a cause. She had been hospitalized four times in the last three months for severe muscle spasms. *Id.* She weighed 133 pounds. Her joints and extremities were normal. *Id.* Dr. Barr's impression was probable depression and anxiety reaction, and chronic fatigue syndrome and fibromyalgia by history. Med. recs. at Ex. 9, p. 2.

On August 17, 1997, petitioner went to St. Edward Mercy Medical Center Emergency Room, complaining of respiratory difficulties which began Friday. Med. recs. at Ex. 10, p. 2. She had spasms in her back and had been hospitalized four times within the last five months. She had difficulty walking and was unable to straighten up. The onset was in March 1997. This

time, the upper back spasms made it hard to breathe. Her four hospitalizations resulted in a diagnosis of muscle tension. She had herniated discs. The last hospitalization, petitioner had trigger point injections. *Id.* She had daily pain which was worse in the last two days. She could not sit the night before. She had more stress with her move from Louisville. In October 1995, her boss in the U.S. Marshal's Service assaulted her. She was on leave from the Marshal's Service. On examination, petitioner was lying still on her right side, crying. She had shallow respiration. Her lungs were clear. She complained of pain and cried out with light palpation of the interscapular areas. Petitioner was admitted to the hospital. *Id.*

From August 17-19, 1997, petitioner was at St. Edward Mercy Medical Center. Med. recs. at Ex. 10, p. 3. Dr. Barr wrote the history and physical. She saw petitioner in her office on Thursday, August 13, 1997. Petitioner was new to Fort Smith, Arkansas. She had a history of severe muscle spasms causing entire lower back pain. Although petitioner said she had been hospitalized four times in the last five months for this, Dr. Barr could find only one hospitalization in the records petitioner gave her. On Friday night, petitioner vacuumed her house and was doing fine. When she bent over to put a gallon of milk in the refrigerator, she felt a pull in her upper back. On Saturday, her left side became weak and tingling, and the pain worsened. It was intolerable on August 17th. She hurt so much, she could not breathe, walk, or straighten. She was given Demerol, Nubain, and Ativan in the ER and still bitterly complained of pain. *Id.* Petitioner said she was on leave and had been a U.S. Marshal for 14 years. *Id.* Two years ago, a sexual harassment incident occurred at work and, since then, she had been ill to the point where her doctor requested she go on leave for a year. Med. recs. at Ex. 10, pp. 3-4. Her

last diagnosis was post-traumatic stress disorder with psychosomatic syndrome. Med. recs. at Ex. 10, p. 4.

Petitioner told Dr. Barr she had no problems with headaches and had chronic bronchitis in the winter over the last three years. *Id.* Petitioner reported she had six incidents of bronchitis over the prior winter and pneumonia years ago. She had a known mild mitral valve prolapse. She had no history of palpitations or hypertension. *Id.* She had occasional problems with heartburn and indigestion. She had a negative GI work-up several times. She had irritable bowel syndrome. *Id.* She was on Ortho Tri-Cyclen for period regulation. Her spasms started in March 1997. They were incapacitating. No etiology was found. She was finally diagnosed with fibromyalgia. She told Dr. Barr she had four herniated discs in her thoracic spine. She broke her arm as a child. Petitioner had psychiatric problems at the time all stemming from the sexual harassment. She saw a psychologist and psychiatrist before she moved to Arkansas. *Id.*

Petitioner was well-nourished. Her pulse was 82 and her temperature 98.2°. She cried out in pain when Dr. Barr palpated her back, especially the upper back around the spine area and into the shoulders. Strength and movement in all extremities were normal. *Id.* Her deep tendon reflexes were intact. Med. recs. at Ex. 10, p. 5. Dr. Barr diagnosed petitioner with acute muscle spasm, history of fibromyalgia, and history of post-traumatic stress syndrome with psychosomatic conversion (based on her psychiatrist's letter). Dr. Barr prescribed Robaxin and pain medicine. *Id.*

On August 17, 1997, petitioner had an x-ray of her thoracic spine. Med. recs. at Ex. 10, p. 9. She had mild dextroscoliosis and mild anterior degenerative marginal spurring at multiple levels through the mid-thoracic spine. *Id.*

On August 17, 1997, petitioner had an x-ray of her chest. There was a pectus excavatum deformity, but no active cardiopulmonary disease. Med. recs. at Ex. 10, p. 10.

On August 21, 1997, petitioner saw Dr. Thomas F. Florian at the Pain Recovery Center. Med. recs. at Ex. 14, p. 1. Petitioner had midthoracic pain radiating into her arms and headaches. The problems started with muscle tension and flexing her head forward so that her chin was on her chest. She had a work-up in a hospital without a diagnosis and was told to have physical therapy which helped her. Something, however, popped and she had pain between her shoulder blades. An MRI scan in March was negative. There were some abnormalities in an MRI scan in June. She has had four hospitalizations for this pain. Her past history was negative for psychiatric disease. She was diagnosed with post-traumatic stress disorder but still has pain and severe fatigue. She was told she has fibromyalgia. Neurologists have found no neurologic impairment. She was on administrative leave as a deputy U.S. Marshal after a politically-appointed Marshal assaulted her. This was one of the reasons for her post-traumatic stress. *Id.*

On physical examination, petitioner had 11 of 18 tender points to make a diagnosis of fibromyalgia. Med. recs. at Ex. 14, p. 2. Dr. Florian recommended Ambien. *Id.*

On August 21, 1997, petitioner returned to St. Edward Mercy Medical Center ER, complaining of severe back pain. She said she was unable to walk. Petitioner became tearful and abrasive. The staff discussed fibromyalgia. Med. recs. at Ex. 10, p. 13.

On August 25, 1997, petitioner had a sed rate of 77 (normal runs from 0-20) and a C-reactive protein of 19 (normal runs from 0-0.49). Med. recs. at Ex. 14, p. 3.

On August 28, 1997, petitioner had an echocardiography which showed mild pulmonary hypertension. There was no mitral valve dysfunction. Med. recs. at Ex. 9, p. 3.

From September 2-11, 1997, petitioner was in St. Edward Mercy Medical Center for intractable pain. Med. recs. at Ex. 10, p. 15. She was discharged with a diagnosis of intractable pain and spondyloarthropathy. *Id.* Since her last admittance, she had become much better, but this did not last very long. She was brought to the medical center that morning by her husband who said she was dying. Petitioner was again in a great deal of severe pain, nausea, vomiting, and no eating. She could not walk and could not eat because of the pain. *Id.* Her right index finger and her right ring finger were quite swollen and tender over the MP and PIP joints. The worst pain was between her shoulder blades. On testing, her globulin was a little high at 4.2. Her iron was low at 16. X-ray of the right hand showed minimal narrowing and arthritic changes at the interphalangeal joints and the metacarpophalangeal joints. X-ray of the lumbar spine showed disk space narrowing at the L5-S1, degenerative changes of the posterior elements, and rotoscoliosis. X-ray of the dorsal spine showed disk narrowing, and degenerative and hypertrophic changes. X-ray of the cervical spine showed straightening of the normal cervical lordosis and foraminal spurring. *Id.*

Dr. Kareus, neurologist, felt that this was a chronic diffuse pain without any neurological injury. Dr. Deneke, rheumatologist, felt that the pain might be facet inflammation, possibly even spondylitis or spinal arthropathy. He suggested that the anemia might be one of chronic disease. He agreed with the prior diagnosis of post-traumatic stress disorder with depression aggravating the pain. None of petitioner's work-up really showed anything. By the ninth hospital day, her pain was under control. Med. recs. at Ex. 10, p. 16.

On September 2, 1997, Dr. John Kareus, a neurologist, wrote a consultative report. Med. recs. at Ex. 10, p. 2.. Petitioner's symptoms began about two years previously (putting onset in

1995) when she had chronic insomnia and irritable bowel symptoms. She had recurrent upper respiratory tract or bronchitis infections. She was diagnosed with post-traumatic stress syndrome with depression. She stopped working in November 1996. In March 1997, she awoke in the middle of the night with a terrible headache. She had an intense pressure sensation over the back of her head and a pulling of her neck. She went to the ER and was diagnosed with possible meningitis. She had continued problems with persistent pain and lost six pounds in two days because she could not eat anything. *Id.* She was admitted to the hospital with headaches. She stayed in the hospital for four or five days (March 23-28, 1997). Her headache improved but she continued to have tightness in her upper shoulders and the back of her neck. This was diagnosed as tension headache. She was sent to rehabilitation. She was in physical therapy and gradually improving until April 23rd or 24th, 1997 when in physical therapy, she did some lateral pulls and heard a couple of pops between her shoulder blades. She had intense, scalding pain between her shoulder blades. She went for a seven- or eight-hour car ride the next day, and woke in the middle of the night with intense pain and spontaneous abnormal arm movements on the left side. *Id.* She was treated with ultrasound which did not help. She continued on pain medication, principally narcotics. She continued to have problems and insomnia. She could not lie down. She developed an electric shock-like sensation down her left arm and then her right arm. Med. recs. at Ex. 10, p. 23. Now, her left arm felt numb and heavy. Her final diagnosis after MRI scans of her total spine was a small herniated disk at T8-9 and T10-11. She was diagnosed with fibromyalgia. She continued to have pain between the shoulder blades, radiating up into her neck and down her arms. She lost 15 pounds over the last few months. Her husband had to help her to turn over in bed. She had an elevated sediment rate in the 80s and elevated C reactive protein.

Dr. Florian said she needed medical attention and would not treat her. She continued to have weakness and fatigue. She had been treated with multiple injections, trigger point and facet injections. She had taken Paxil for the last two years, Trazodone to sleep and Ambien to help her sleep. She was on Zanax to sleep. She reported intermittent fevers up to 101.4° for the last few weeks. *Id.* Pain radiates from the center of her thoracic spine into her anterior chest. She had been diagnosed with chronic fatigue syndrome and fibromyalgia. She had an elevation of Epstein Barr. She had been diagnosed with mitral valve prolapse the last few years along with irritable bowel syndrome. The remainder of her medical history was negative. "She reiterates repeatedly that she was very healthy until two years ago." *Id.* (That would put onset in 1995.) "She was very athletic running six miles without difficulty, doing pushups, lifting weights without any problem and that this has all be[en] a pronounced change in her condition since." *Id.* During her hospitalization August 17-19, 1997, she had a sed rate of 43. She has been taking Nortriptyline, Paxil, Lodine, and in the hospital was given Demerol and Phenergan. Med. recs. at Ex. 10, p. 24.

On examination, petitioner had 5/5 strength in her upper and lower extremities. She had give away weakness in all muscle groups, but no specific weakness was detected. There was no change in tone, atrophy, fasciculations, or abnormal movements. Reflexes were intact symmetrically at the biceps, triceps, knees and ankles. Plantar stimulation was downgoing bilaterally. There were no pathologic reflexes. She did finger to nose and heel to shin accurately without difficulty. *Id.* Examination of the thoracic spine revealed multiple areas of tenderness and muscle hypersensitivity in the intrascapular area and also the lower thoracic and upper

lumbar spine bilaterally. Med. recs. at Ex. 10, p. 25. Dr. Kareus' impression was chronic diffuse pain without evidence of neurologic injury. *Id.*

On September 4, 1997, petitioner saw Dr. James S. Deneke for a consultation. Med. recs. at Ex. 10, p. 26. Her back pain dated to April 1997 when she was doing pulls with her arms in physical therapy. Two weeks ago, she developed increased pain while mopping the floor. Her hips occasionally ached since the spring. She had had trouble staying asleep since December 1995. She was diagnosed with post-traumatic stress syndrome and depression in 1995, associated with nausea, vomiting, fatigue, and insomnia. Lodine had caused some stomach upset. She had also been on Oxycontin and Macrodantin. She had had irritable bowel for two years. *Id.* She lost 10-12 pounds. Med. recs. at Ex. 10, p. 27. She had variable appetite with slightly decreased hearing. She had occasional temperature to 100-100.5° without chills or sweats. *Id.* She had occasional shortness of breath with pain. She had frequent diarrhea for eight months. She was nervous and depressed, but denied memory loss. She weighed 125 pounds. Her deep tendon reflexes were 2+ and symmetrically intact. *Id.* She had good range of motion in her neck and slight discomfort. Her shoulder had good range of motion without pain on motion. *Id.* Her chemistry was remarkable for increased globulins at 4.2 (with the normal range being 2.2 to 3.5). Med. recs. at Ex. 10, p. 28. Her iron was 16 (with the normal range being 41 to 60). Dr. Deneke's assessment was unexplained pain, primarily in the back which could represent facet inflammation, possibly even spondylitis or spinal arthropathy; anemia of chronic disease; history of fever; inflammatory bowel, history of post-traumatic stress and depression aggravating the above. *Id.*

On September 4, 1997, petitioner saw Dr. Chris Van Asche, a gastroenterologist. Med. recs. at Ex. 10, p. 29. Dr. Deneke and Dr. Barr wanted him to evaluate petitioner for possible inflammatory bowel disease. She had about 18 months of crampy abdominal pain and diarrhea as well as heartburn and dyspepsia. She was on multiple drugs over the past year or two for pain, including many of the nonsteroidals, Ultram, narcotics, etc. She used to have a lot of diarrhea, but, over the last week or so, she was mainly constipated. The use of narcotics might explain her constipation. She denied bleeding, but said her stools were frequently black. She had an iron deficiency anemia with a hemoglobin of 10.6, hematocrit of 31.5, elevated platelet count at 459,000, and an iron that was quite low at 16 with a TIBC of 275 to give her an iron saturation well below 10%. *Id.*

On September 5, 1997, petitioner had a colonoscopy because of diarrhea and iron deficiency anemia. Med. recs. at Ex. 10, p. 17. The preparation was fair in some areas and poor in others. *Id.* The assessment was suboptimal but it was a normal colonoscopy to the cecum. Med. recs. at Ex. 10, p. 18.

On September 5, 1997, petitioner had an esophagogastroduodenoscopy for dyspepsia and iron deficiency anemia. Med. recs. at Ex. 10, p. 19. It was normal. *Id.*

On September 6, 1997, petitioner had a small bowel series. She had a slow transit which might be due to her lack of walking and possibly medication. There was no specific abnormality. Med. recs. at Ex. 10, p. 44.

On September 8, 1997, petitioner saw Dr. John Swicegood in consultation. Med. recs. at Ex. 10, p. 32. She was very physically active and fit until a year ago, according to petitioner. She developed diffuse fibromyalgia with associated spine and joint pain. She developed a

chronic low grade fever. She stated she had a number of positive rheumatoid factors. Dr. Swicegood switched petitioner from Demerol to a Duragesic patch. Dr. Swicegood administered epidurals for pain relief. *Id.*

On September 10, 1997, petitioner had blood tests showing high sed rates of 75 and 85 (normal was between 0-20). Med. recs. at Ex. 10, p. 45.

On September 29, 1997, petitioner had a whole body bone scan. There was mild uptake in the thoracic spine, cervical spine, inferior aspect of the sacroiliac joints, knees and hips, suggesting an arthritis-type distribution. Med. recs. at Ex. 10, p. 48.

On November 26, 1997, petitioner Saw Dr. Robert M. Valente, a rheumatologist at the Mayo Clinic. She had a history of salmonella food poisoning which was quite severe when she was 12. Med. recs. at Ex. 11, p. 6. Dr. Barr requested evaluation for possible spondyloarthropathy. Petitioner came with 500 pages of medical records and eight pounds of x-rays. She tearfully told Dr. Valente of her supervisor's sexual assault of her in October 1995. Her complaint was ignored and fostered a stress disorder over the subsequent months, including repeated episodes of nausea, vomiting, poor sleep, and increasingly severe bad dreams about prior physical hazing when she was at the U.S. Marshal academy. She was diagnosed with depression and given counseling and medication therapy by June 1996. She was put on administrative leave. Over the subsequent months, she developed aches and pains diagnosed as fibromyalgia. In November 1996, she developed increasing symptoms of irritable bowel-like distress in addition to rib cage pain, making it hard for her to breathe. In March 1997, she was unable to move with severe posterior cervical spine pain. *Id.* She was in extreme distress, crying on the couch. Med. recs. at Ex. 11, p. 7. Dr. Valente diagnosed early spondyloarthropathy. He

suspected she had a reactive spondyloarthropathy and petitioner's prior exposure to salmonella was an important historical factor. *Id.* He also diagnosed petitioner with narcotic-dependent chronic pain syndrome with features of fibromyalgia. Med. recs. at Ex. 11, p. 8. He also diagnosed petitioner with post-traumatic stress disorder/depression. Starting legal proceedings for sexual harassment would be difficult for her. He also diagnosed her with narcotic and antidepressant-associated constipation, irregular menses, and allergies or intolerance to codeine and antihistamines. *Id.*

On November 26, 1997, Dr. Valente saw petitioner again. *Id.* Laboratory studies revealed a mild normocytic anemia, sedimentation rate of 35, a normal serum ferritin, positive HLA-B27, mildly elevated alkaline phosphatase with an otherwise normal 13-channel chemistry group, negative rheumatoid factor, negative Hepatitis B and C serology, and a normal urinalysis. *Id.* Petitioner's gamma globulin was elevated at 1.98 (normal range being 0.7-1.7). Med. recs. at Ex. 11, p. 2.

On December 16, 1997, petitioner saw Dr. Deneke, the rheumatologist. Med. recs. at Ex. 9, p. 6. She had been hospitalized in September for chronic pain, presumed spondyloarthropathy.[4] Over Thanksgiving, she was seen at the Mayo Clinic, where they agreed she had spondyloarthropathy. She was placed on Prednisone. She was also taking Voltaren XR. Dr. Deneke suggested Methotrexate or Azulfidine. She was on Trazodone at night, Alprazolam at night and occasionally in the morning, Paxil, and Norgesic patch every third day. The Mayo

[4] Spondyloarthropathy is "disease of the joints of the spine." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1743.

Clinic recommended physical therapy and splinting, which was not accomplished because insurance would not okay it. Petitioner weighed 134 pounds. *Id.*

On January 16, 1998, petitioner saw Dr. Deneke. Med. recs. at Ex. 9, p. 8. She weighed 140 ½ pounds. Petitioner seemed better. *Id.*

On February 13, 1998, petitioner was not better. Pain in her left wrist awakened her. Med. recs. at Ex. 9, p. 12.

On March 19, 1998, petitioner saw Dr. Deneke. Med. recs. at Ex. 9, p. 31. Despite improvement in her hand, she complained of increased pain in her hips, and weakness in the legs and arms for about a month. She complained of increasing numbness in her legs with electric shocks. Her arms sometimes shook as she lifted them. Petitioner weighed 155 ½ pounds. On examination, she had no neurologic deficits. In the upper and lower extremities, her deep tendon reflexes were intact and she had intact strength. Dr. Deneke was worried that he was seeing some accentuation more related to depression and chronic pain rather than nerve injury or flare of arthritis. *Id.*

On April 24, 1998, Dr. Deneke wrote a letter, stating his initial contact with petitioner was on September 4, 1997. She gave a history that her back pain began in April 1997. She had a history of nonspecific symptoms that were diagnosed as post-traumatic stress and depression, resulting in her being unable to work since November 1996. Med. recs. at Ex. 9, p. 18. She dated difficulty sleeping to December 1995. She manifested inflammatory arthritis consistent with spondyloarthropathy. This might be an atypical form of ankylosing spondylitis. She had had swelling in her fingers. *Id.* Petitioner was limited in her ability to lift, grasp, push and pull, due not only to the problems in her hands but also due to the pain in her spine. The pain, sleep

disturbance and mood disturbance affected her concentration. Med. recs. at Ex. 9, p. 19. Dr. Deneke believed the post-traumatic stress syndrome might have precipitated the activity of the spondyloarthropathy which aggravated her tolerance of the post-traumatic stress and depression. The post-traumatic stress syndrome and depression made it more difficult for her to deal with her spondyloarthropathy. The combination of these disorders produced a chronic pain syndrome. *Id.*

On May 8, 1998, petitioner saw Dr. Deneke with increased problems, primarily due to a trip back to Lexington for a hearing. She had extended time in the airports, flight, and schedule. Med. recs. at Ex. 9, p. 21.

On May 21, 1998, petitioner reported that she had two blackout spells since Saturday. Med. recs. at Ex. 9, p. 24. She was unable to stand and leaned or walked to the side. She had visual disturbance and severe nausea during the spell. That morning, she had severe back pain and her stomach was bloated. She had stomach pain. *Id.*

On June 30, 1998, petitioner reported she was on thyroid replacement. She had a lot of neck stiffness and rib pain. *Id.*

On July 1, 1998, petitioner saw Dr. Deneke. She complained of increased pain in her rib area for about two weeks and decreased motion in her neck for two to three weeks. In the past several weeks, she had not been resting well at night and was having increasing nightmares. She had to go back and forth to court to testify and had been in counseling for about a year for post-traumatic stress. She looked better. Med. recs. at Ex. 9, p. 29.

On August 11 and 14, 1998, petitioner saw Dr. Phillip W. Barling, Ph.D., a clinical psychologist, at the request of Drs. Barr and Deneke. Med. recs. at Ex. 12, p. 1. Her chief complaints were depression and chronic pain. She described herself as only one of five women

in a class of 40 training to be U.S. marshals and a progressive pattern of verbal and physical harassment. She developed a deep depression as a result of that harassment. Just a few weeks prior to graduating from the academy, she had a severe physical injury to her knee that she felt one of her instructors intentionally inflicted on her. She went on to complete her graduation examinations including a severe physical test. At the end of that physical training exam, she lapsed and dissociated. While in Louisville, KY, she described a progressive pattern of gender discrimination and harassment by a supervisor. He had previously been her supervisor in Miami. She rebuffed his sexual advances there. *Id.* (The second page of this report is missing.)

On August 20, 1998, petitioner returned to Dr. Barling. Med. recs. at Ex. 12, p. 2. He diagnosed her with depressive disorder, post-traumatic stress disorder, ankylosing spondylitis, fibromyalgia, extreme psychosocial stresses (severe chronic stress, continued legal suit, physical disability, and associated financial stress).

On September 14, 1998, petitioner telephoned that she had had episodes of dizziness, nausea, and intermittent vomiting for three weeks. Her stomach burned as if she had an ulcer. Med. recs. at Ex. 9, p. 41.

On September 16, 1998, petitioner saw Dr. Brian H. Rodgers, complaining of abdominal pain. Med. recs. at Ex. 9, p. 43. She passed blood in her stool the prior evening. Dr. Rodgers assessed gastrointestinal bleeding and abdominal pain. *Id.* He also assessed ankylosing spondylitis and fatigue. Med. recs. at Ex. 9, p. 44. He recommended a colonoscopy. *Id.*

On September 21, 1998, petitioner came to the Cooper Clinic for a scheduled CT of her abdomen. Med. recs. at Ex. 9, p. 45. She said that last Tuesday, she had severe abdominal cramping and bloody stools ever since. She had been in bed the prior three days with severe

fatigue. She requested a B12 level and stated that some of her previous co-workers had tested positive for lead poisoning. She said when she vomited, she had a metallic taste in her mouth. The clinic would check her B12, folate, and serum lead levels. *Id.*

On September 24, 1998, the Cooper Clinic informed petitioner that her B12, folate, and serum lead levels were within normal. *Id.*

On September 29, 1998, petitioner saw Dr. Dale W. Asbury. Med. recs. at Ex. 9, p. 48. She had a multiple myriad of problems. In 1985, she had problems at her workplace where she was a U.S. marshal. Depression followed this with insomnia. She has had a number of symptoms following that including persistent unrelenting nausea and vomiting and fevers for the past couple of years. She had drenching night sweats. She saw a number of doctors without much improvement. Dr. Deneke and the Mayo Clinic diagnosed her with ankylosing spondylitis.[5] She was on Methotrexate[6] and Azulfidine for this problem. She had multiple hospitalizations over the last two years. She took Duragesic patches. Her most recent complaints were blackout spells, inflammatory nodes, dizziness, vertigo, hematochezia,[7] and

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[5] Ankylosing spondylitis is "a form of degenerative joint disease that affects the spine. It is a systemic illness of unknown etiology, affecting young persons predominantly, and producing pain and stiffness as a result of inflammation of the sacroiliac, intervertebral, and costovertebral joints; paraspinal calcification, with ossification and ankylosis of the spinal joints, may cause complete rigidity of the spine and thorax." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1742.

[6] Methotrexate may have adverse effects: blood and bone marrow problems (fever, chills, sore throat, unusual bruising or bleeding, black, bloody or tarry stools), lung problems (unexplained shortness of breath, coughing, or wheezing), stomach problems (diarrhea, abdominal pain), unusual fatigue, nausea, vomiting, decreased appetite, hair loss, dizziness, headache, drowsiness, or blurred vision. www.drugs.com/methotrexate.html.

[7] Hematichezia is "the passage of bloody feces." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 824.

vomiting. She was medically disabled from the U.S. Marshals. Dr. Asbury's assessment was ankylosing spondylitis, depression, hypothyroidism, and lower gastrointestinal issues. *Id.*

On September 29, 1998, petitioner was tested for mercury. The result was negative. Med. recs. at Ex. 10, p. 51.

On October 13, 1998, a scheduled colonoscopy could not proceed because the preparation was very poor and would not allow appropriate visualization. Med. recs. at Ex. 9, p. 55.

On October 14, 1998, another colonoscopy proceeded but without visualization of 30% of the mucosa due to poor preparation. The examination was normal for what was seen. Med. recs. at Ex. 9, p. 56. Dr. Van Asche saw nothing that would cause abdominal pain or bleeding. Med. recs. at Ex. 9, p. 57.

On October 27, 1998, petitioner saw Dr. Asbury with rhonchi, rales, and chest coughing. She had fever and felt lousy. Dr. Asbury diagnosed bronchitis. Med. recs. at Ex. 9, p. 59.

On October 29, 1998, petitioner saw Dr. Deneke to follow-up her spondyloarthropathy and chronic pain. She was concerned about her lack of energy and burning pain around her left shoulder blade. She continued to have problems with her neck. Med. recs. at Ex. 9, p. 60. Dr. Deneke encouraged petitioner to increase her Trazodone.

On November 18, 1998, petitioner went to the Cooper Clinic. Med. recs. at Ex. 9, p. 65. She gave a history of having a high fever in October 1996 for three weeks. She had temperature up to 103° and extreme fatigue and flu-like symptoms. She was never seen by anyone. It resolved spontaneously. She had a loss of energy since then and was exhausted. In November 1996, she had five nights of fever. In Christmas, her fatigue continued with low-grade fever. She was tested for mononucleosis and HIV, but was negative. *Id.* In March 1997, she could not

move from bed. A spinal tap was done in Kentucky. She had diffuse pain. In April 1997, she was hospitalized for two weeks with catatonia. She was not ill between spells of fever. She had back and neck pain. She moved to Arkansas and has severe pain. The Mayo Clinic diagnosed ankylosing spondylitis. She has episodic temperatures up to 103°. In the last six months, she had had severe fatigue. She had spreading joint problems. She had fever of 12 days, usually to 102°, and profound sweats. She had recurrent bouts of bronchitis. She had mild headache. *Id.*

On November 18, 1998, petitioner saw Dr. Asbury for a breast and pelvic exam which was normal. Med. recs. at Ex. 9, p. 67. Also on that date, she was tested for hepatitis B antibody which was positive. Med. recs. at Ex. 10, p. 54.

On November 24, 1998, petitioner tested positive for Parvovirus B-19 antibody IgG. Med. recs. at Ex. 9, p. 72. She had a reading of 4.69, where anything over 1.20 was positive. *Id.* Her IgM was negative. *Id.*

On December 1, 1998, petitioner's white blood cells had an indium scan because of fever of unknown origin. The study was negative. Med. recs. at Ex. 10, p. 55.

On December 9, 1998, petitioner had a follow-up. Her temperature was 98.4°. Her temperature at home was 100°. Med. recs. at Ex. 9, p. 69.

On December 30, 1998, petitioner saw Dr. Deneke. Med. recs. at Ex. 9, p. 77. She complained of increased pain over the last couple of months. She had not been swimming regularly. She complained of pain in her back. *Id.*

On January 2, 1999, petitioner went to St. Edward Mercy Medical Center ER, complaining of joint pain and numbness to her face, hands, and feet. Med. recs. at Ex. 10, p. 58. The onset was New Year's Eve. She was worsening. She said she usually got this every six

weeks lasting 24 hours, but now the symptoms were lasting longer and were more severe. *Id.* She had a history of ankylosing spondylitis and a history of recurrent flares of pain. She was diagnosed 18 months previously. She had severe stomach pain with vomiting but no diarrhea. She was too sick to take her medications for two days. She had a long history of chronic pain. *Id.* She was diagnosed with gastroenteritis and possible peptic ulcer disease. Med. recs. at Ex. 10, p. 59. Petitioner was admitted to the hospital that day and discharged on January 4, 1999. Med. recs. at Ex. 10, p. 62.

On January 4, 1999, petitioner had an esophagogastroduodenoscopy because of persistent nausea and vomiting. Med. recs. at Ex. 10, p. 60. Biopsies were pending but otherwise she had a normal gastroscopy. *Id.* Dr. Van Asche removed a 5 or 6 mm polyp in the proximal stomach. *Id.* The biopsies showed a mild amount of chronic inflammation but no acute activity. Med. recs. at Ex. 10, p. 64.

On January 15, 1999, petitioner saw Dr. Asbury after having been in the hospital a couple of days previously for nausea. Med. recs. at Ex. 9, p. 83.

On January 18, 1999, petitioner had an MRI of her brain with and without gadolinium. Med. recs. at Ex. 10, p. 81. She had negative intracranial findings. There was a small 1 cm Tornwaldt's cyst in the posterior nasopharynx eccentric to the left of no clinical significance. There was minimal mucosal thickening of the left maxillary sinus inferiorly. *Id.*

On January 23, 1999, petitioner saw Dr. Asbury, complaining of nausea with vomiting. Her weight was stable at 134 pounds. She said she talked to a doctor at Baylor[8] who thought the

[8] Presumably, this "doctor" is Bonnie Dunbar, who is not a medical doctor but a Ph.D. She testified at the Omnibus hearing on whether hepatitis B vaccine can cause demyelinating illnesses. Bonnie Dunbar's brother has a pending petition alleging hepatitis B caused his illness.

cause of her problems might be hepatitis B vaccine. Apparently this doctor had a number of cases like this. Med. recs. at Ex. 9, p. 84.

On February 9, 1999, petitioner saw Dr. Riley D. Foreman, a cardiologist, at the referral of Dr. Asbury, to evaluate petitioner's squeezing chest pain. Med. recs. at Ex. 9, p. 86. Petitioner stated she had a long history of some palpitations. An echocardiogram in Louisville, KY showed some mild prolapse of the mitral valve. She had been having increasing episodes of palpitations consisting of a very fast racing heartbeat occurring every two or three weeks, but when they occurred, she had several episodes over a four- or five-day period. Some of these episodes were associated with syncope. She said she had three syncopal episodes this summer associated with palpitations and shortness of breath. She had dyspnea with these episodes. *Id.* More recently, she had squeezing chest pain associated with the palpitations. She had increasing exertional fatigue and increasing dyspnea on exertion. *Id.*

Petitioner noted increasing fatigue and fatigue which was completely out of proportion to her rheumatologic symptoms. Med. recs. at Ex. 9, p. 87. She denied fever, chills, or night sweats. Her weight was 135 pounds. Her heart beat at a normal rate. Her motor examination was nonfocal and she moved all extremities equally. *Id.* The EKG showed normal sinus rhythm. Med. recs. at Ex. 9, p. 88.

On February 24, 1999, petitioner had an echocardiogram. Med. recs. at Ex. 9, p. 96. She did not have mitral valve prolapse. She had a normal left ventricular systolic performance. *Id.*

On February 24, 1999, petitioner had a stress test. She had good exercise tolerance, a normal stress ECG, and normal stress echocardiographic study. Med. recs. at Ex. 9, p. 99.

On March 11, 1999, petitioner saw Dr. Deneke. Her nausea and vomiting seemed to have been due to Methotrexate. It went away after she stopped taking it and returned when she resumed taking it. She weighed 157 ½ pounds. Med. recs. at Ex. 9, p. 103.

On March 31, 1999, petitioner saw Dr. R. Peter Fleck for an electrophysiology consultation. Med. recs. at Ex. 9, p. 104.

On April 12, 1999, petitioner saw Dr. Deneke. Her neck had been bothering her more lately. She weighed 136 pounds. Med. recs. at Ex. 9, p. 107.

On May 27, 1999, petitioner saw Dr. William Knubley, a neurologist, for headache and somnolence. Med. recs. at Ex. 10, p. 85. She had a history of progressive back and spine pain diagnosed in the last couple of years at the Mayo Clinic as ankylosing spondylitis. She developed hypothyroidism about a year previously. She had no severe headaches. Over the last year or so, she developed progressive paroxysmal tachycardia. She had some severe vertigo with nausea earlier in 1999 thought due to Methotrexate. She was off that now and that went away, but apparently she had more problems with dizziness and presyncope. She had episodes where she was lightheaded and even passed out. She never suffered from any severe headaches. Cardiology gave her nodal ablation on May 27, 1999 without any complications. After a number of medications, she had low blood pressure and was difficult to arouse. *Id.* Her echocardiogram that day was unremarkable. Med. recs. at Ex. 10, p. 86. On examination, her reflexes were normal. Med. recs. at Ex. 10, p. 87. Dr. Knubley's impression was reduced sensorium with no localizing neurologic findings or evidence to implicate central nervous system infection, stroke or seizure. He suspected petitioner's susceptibility to medicines and the difference in medications plus her hypertension partly induced by medicines, volume depletion, and

interacting factors caused this. Her headaches were likely due to her ankylosing spondylitis with referred pain in her neck due to prolonged immobility. She had slightly decreased pin prick and vibration sense in her left lower extremity likely due to her ankylosing spondylitis. *Id.* Petitioner's globulin was still high at 3.6 (the normal range being 2.2-3.5). Med. recs. at Ex. 10, p. 91.

On May 27, 1999, petitioner had a CT scan done of her head. Med. recs. at Ex. 10, p. 98. It was normal. There was a subtle area of increased density adjacent to the left frontal horn of the lateral ventricle on the post-contrast images, most likely representing normal vascularity in this region. *Id.*

On July 9, 1999, petitioner saw Dr. Fleck for a follow-up to paroxysmal supraventricular tachycardia status post-ablation. Med. recs. at Ex. 9, p. 128. She was doing very well. Since her ablation, she had no recurrence of fast heart rates. She was in a car accident and the air bags injured her arms and chest. *Id.*

On July 20, 1999, petitioner saw Dr. Asbury. Med. recs. at Ex. 9, p. 130. He stressed doing range of motion exercises and conditioning. *Id.*

On August 16, 1999, petitioner saw Dr. Asbury, complaining of chronic pain and chronic fatigue. Med. recs. at Ex. 9, p. 132. She had loss of appetite. *Id.*

On August 16, 1999, she saw a dermatologist for a rash on her chin since May. She was diagnosed with dermatitis. Med. recs. at Ex. 9, p. 133.

On August 23, 1999, petitioner saw Dr. Asbury, complaining that she was sleeping too much, 24 to 40 hours at a time. She had been nauseated. Dr. Asbury's assessment was that her

oversleeping was most consistent with an overdose of narcotics. He told her to stop the Duragesic which she had been taking a lot of. *Id.*

On September 2, 1999, petitioner saw Dr. Asbury, complaining of vomiting, nausea, vertiginous episodes, and one episode of diarrhea. She felt kind of drunk but did not drink. Med. recs. at Ex. 9, p. 140.

On September 10, 1999, petitioner saw Dr. Michael Gwartney, an otolaryngologist. Med. recs. at Ex. 9, p. 141. She complained of vertigo and told Dr. Gwartney she had some sort of autoimmune process or something related to hepatitis vaccine a few years previously. She got vertigo three to four times a year which lasted sometimes for two or three weeks. Her left ear rang at times. The ringing dated to a shotgun blast by that ear a few years ago. Her vertigo was whirling with associated nausea and vomiting. She spun as opposed to the room spinning. She had an audiogram showing a high frequency sensory neural loss at 4 and 8k in the left ear and everything else was perfectly normal. Her tympanic membranes and canals were clear. Her throat was not inflamed. Dr. Gwartney did not think this was Meniere's disease. *Id.*

On September 10, 1999, petitioner saw Dr. Asbury feeling a lot better from her vertiginous problems with Meclizine. Med. recs. at Ex. 9, p. 142.

On September 24, 1999, petitioner saw Dr. Deneke. She continued to have episodes of vertigo associated with nausea and vomiting. The onset was January. She has intermittent nosebleeds. Her legs were burning and stinging. Med. recs. at Ex. 9, p. 144.

On September 29, 1999, petitioner had an ENG done because of episodic vertigo with nausea and vomiting. Med. recs. at Ex. 15, p. 3. She did not have nystagmus. *Id.*

On October 4, 1999, petitioner saw Dr. Knubley, the neurologist. Med. recs. at Ex. 9, p. 246. He saw her in May at the hospital. In 1998, she had what sounded like possible Lhermitte's symptoms with shock-like sensation in the legs and episodic vertically with a negative ear-nose-throat work-up. "I really could not identify anything on her exam that might suggest MS or any other cause...." *Id.*

On October 7, 1999, petitioner had an MRI of her brain with and without gadolinium. Med. recs. at Ex. 10, p. 108. She had multiple foci of bilateral subcortical and periventricular white matter hyperintensities predominantly in the subcortical distribution, certainly worrisome for MS given her age and the progression from the prior examination. *Id.*

On October 19, 1999, petitioner saw Dr. Knubley for a spinal tap. She had some symptoms including possible Lhermitte's episodes with shock-like sensation down her legs and she complained of leg spasms. She also had some vertigo. An MRI scan done that month showed multiple areas in the white matter suggestive of possible MS. Med. recs. at Ex. 9, p. 147.

Petitioner's October 19, 1999 spinal tap was high for protein (75 when normal is 12 to 60). Med. recs. at Ex. 9, p. 148. Her myelin basic protein was negative. No oligoclonal bands were detected. Med. recs. at Ex. 9, p. 152.

On October 22, 1999, petitioner saw Dr. Fleck, the cardiologist. Med. recs. at Ex. 9, p. 156. She was doing very well from a cardiac standpoint. There was no recurrence of her supraventricular tachycardia. She denied chest pain. Her breathing was comfortable and without difficulty. *Id.*

On October 22, 1999, petitioner saw Dr. Asbury. She came for a biopsy of some nodes in her right inguinal region. On biopsy, there was only a little lipoma but no nodes. Med. recs. at Ex. 9, p. 158.

On November 1, 1999, petitioner saw Dr. Burton Waisbren.[9] Med. recs. at Ex. 16, p. 1. He stated in a record of November 4, 1999 that petitioner "had nothing in her past history[10] before suffering a reaction to the hepatitis B vaccine in 1993 and 1994 except a possibly significant severe salmonella infection when she was twelve years old." *Id.* All the symptoms she had been reporting to doctors primarily in 1996, petitioner now told Dr. Waisbren had occurred after her hepatitis B vaccinations in 1993 and 1994: fever, nausea, abdominal pain, anorexia, insomnia, hallucinations, and severe joint pain of her spine and trunk. After the third hepatitis B vaccination, petitioner said she became chronically ill with severe weakness, fatigue, muscle weakness, dizziness, and weakness in her right hand. *Id.* None of her "excellent physicians" were able to diagnose her difficulties even though she had at least seven hospitalizations. *Id.* A physical examination at his clinic on November 1, 1999 revealed hyperreflexia, absent abdominal reflexes, and paresthesia over the arms and legs. *Id.* Dr. Waisbren diagnosed petitioner with post-vaccinal encephalomyelitis and post-vaccinal demyelinizing disease of the central nervous system. The latter fit best in the category of MS. He prescribed Copaxone. *Id.* In testing Dr. Waisbren performed on November 1, 1999,

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[9] Dr. Waisbren has a website (www.waisbrenclinic.com) in which he lists various essays, including: "It is time to pull the plug on the 'experiment' of universal hepatitis B vaccination in the United States" and "Universal hepatitis B vaccination: is it the sword of Damocles hanging over the head of the American People?"

[10] Obviously, petitioner did not tell Dr. Waisbren about her being sexually assaulted in 1995, followed by post-traumatic stress disorder, psychosomatic symptoms, depression, etc.

petitioner was positive for cytomegalovirus. Med. recs. at Ex. 16, p. 2. She also tested positive for Epstein Barr virus IgG, Herpes II, and Herpes I. Med. recs. at Ex. 16, p. 4. On November 2, 1999, petitioner did not have any reaction to hepatitis B core IgM antibodies or hepatitis B surface antigen. Med. recs. at Ex. 16, p. 7. On November 4, 1999, petitioner's antinuclear antibodies (ANA) were less than 1:40, i.e., negative. Med. recs. at Ex. 16, p. 11. She was positive for candida albicans IgG on November 8, 1999. Med. recs. at Ex. 16, p. 13. On November 10, 1999, petitioner was positive for herpes virus 6 antibody IgM and for herpes virus 6 antibody IgG, the first indicating recent infection or reactivation. Med. recs. at Ex. 16, p. 14.

On November 19, 1999, petitioner saw Dr. Asbury with visual hallucinations. Med. recs. at Ex. 9, p. 161.

On November 29, 1999, petitioner saw Dr. Knubley, the neurologist. Her MS profile was negative although she did have some changes that looked like white matter disease. Petitioner told Dr. Knubley that an "immunologist" named Burton Waisbren felt she had an autoimmune disorder due to hepatitis vaccination, and petitioner gave Dr. Knubley literature. She apparently had a number of symptoms that Dr. Waisbren believed were due to hepatitis vaccination. Dr. Knubley had a long discussion with petitioner and he could not ascertain whether or not she really did have symptoms related to hepatitis B or not, but she and Dr. Waisbren felt she did. "[F]rom my standpoint I do not find any primary neurologic disorder.... I told her that ... she does not have MS...." *Id.* Dr. Waisbren gave her gamma globulins and Copaxone (a treatment for MS) and she felt quite a bit better. It looked as if petitioner had been on a low dose of Neurontin for a week. *Id.*

On January 10, 2000, Dr. Waisbren discussed with petitioner her attempt to get compensation under the Vaccine Program and petitioner agreed to let Dr. Waisbren contact Professor Peter Meyers of the George Washington University Law School legal clinic on her behalf. Med. recs. at Ex. 16, p. 16. He sent a letter to Professor Meyers, dated January 11, 2000. Med. recs. at Ex. 16, p. 19.

On a form dated August 3, 2000, petitioner states that she had a severe adverse reaction to the hepatitis B series in late 1994/1995 (petitioner actually received hepatitis B vaccination in late 1993 and early 1994) which resulted in severe autoimmune reactions, including reactive arthritis, autoimmune hypothyroidism, inflammatory bowel disease, and numerous brain and spinal lesions. Med. recs. at Ex. 9, p. 187.

On August 9, 2000, petitioner complained of less vision in her right eye which began on August 3, 2000 in the early morning with stabbing pain. Her vision decreased since then. She had a nosebleed that morning. She was seen at the eye group and given Prednisone. Her vision was getting better until that morning when it began to decline until it became very dim. She was seeing floaters. Med. recs. at Ex. 9, p. 188.

On August 11, 2000, petitioner saw Dr. Asbury. She had seen Dr. Clara Price a couple of times over the last several days with pain in her eye and some visual disturbances. Funduscopic examination of the eye was performed and it was difficult to view her fundus because of opacification. Med. recs. at Ex. 9, p. 189.

On August 14, 2000, petitioner saw Dr. Kenneth W. Wallace, an ophthalmologist. Med. recs. at Ex. 17, p. 2. Petitioner had noticed a decrease in vision in her left eye. She had been on Homatropine drops. On fundus examination, Dr. Farris could not identify the cause of the visual

loss in the eye. Because of her MS syndrome, it is possible she developed a retrobulbar neuritis in the left eye and the visual loss might be neurological rather than uveitic. He stopped her Homatropine drops. He would check her on August 15th to see if her pressure came down. *Id.*

On August 15, 2000, petitioner saw Dr. Wallace. Med. recs. at Ex. 17, p. 3. Her pressure was down to normal and her vision had stabilized. Petitioner had such a little uveitis that Dr. Wallace did not think it accounted for her vision loss. He thought it was more likely optic neuritis associated with her MS. He made an appointment with Dr. Bradley Farris, a neuro-ophthalmologist. *Id.*

On August 22, 2000, petitioner had an MRI of her brain with and without gadolinium. Med. recs. at Ex. 9, p. 190. There were multiple foci of bilateral subcortical and periventricular white matter hyperintensities similar to the previous examinations on January 18, 1999 and October 7, 1999. Again a demyelinating process could be considered. Med. recs. at Ex. 9, p. 191.

On August 28, 2000, Dr. Waisbren retested petitioner and she was still positive for cytomegalovirus. Med. recs. at Ex. 16, p. 22. On August 30, 2000, she was still negative for ANA. Med. recs. at Ex. 16, p. 23. On the same date, she was positive for HLA-B27, HLA-DR4, HLA-DR53, and HLA-DQ3. Med. recs. at Ex. 16, p. 25.

On August 29, 2000, petitioner saw Dr. Bradley K. Farris, a neuro-ophthalmologist. Med. recs. at Ex. 17, p. 1. Slit lamp examination demonstrated no evidence of active intraocular inflammation of either eye. The rest of her neuro-ophthalmological examination was entirely within normal limits. He explained to petitioner that she had obviously quite well responded to topical steroid therapy for her bilateral iritis. She had some type of systemic autoimmune

process, but Dr. Farris could not be sure this was truly a primary demyelinative disease such as MS. He did not think she had any optic neuritis. He did think petitioner had significant functional overlay. He reassured her she would improve and have no permanent visual problems from her recent inflammation. *Id.*

On February 2, 2001, petitioner saw Dr. Deneke. Med. recs. at Ex. 9, p. 198. Her pain improved on Celebrex. She still had frequent vomiting. She had one episode of optic neuritis in the right eye and loss of vision, but regained some. She had uveitis. She was again having visual loss. There were no signs of inflammation in her joints. She did not have the type of uveitis usually associated with anklyosing spondylitis. More bothersome was that she developed optic neuritis along with taking Copaxone. *Id.*

On February 19, 2001, Dr. Waisbren retested petitioner and she was positive for cytomegalovirus. Med. recs. at Ex. 16, p. 29. She was also positive for Epstein Barr virus IgG. Med. recs. at Ex. 16, p. 30. She was still positive for herpes virus 6 antibody IgG. Med. recs. at Ex. 16, p. 32.

On February 27, 2001, petitioner saw Dr. Swicegood at Dr. Asbury's request. Med. recs. at Ex. 10, p. 120. The Duragesic patch was no longer helping her pain. Petitioner said she had a very active and healthy lifestyle until about four or five years previously (which would put onset in either 1996 or 1997). *Id.* She described significant gastroesophageal reflux and unexpectedly threw up her food or medications. Med. recs. at Ex. 10, p. 121. There were no fever, chills, or weight loss. Med. recs. at Ex. 10, p. 122. Reflexes were brisk at 3+ in the upper extremities, and 4+ with extreme hyperreflexia in the lower extremities. Plantar responses were equivocal. Med.

recs. at Ex. 10, p. 123. Dr. Swicegood concluded petitioner had MS, and degenerative spine and joint disorder. *Id.* Dr. Swicegood gave petitioner a prescription for Methadone. *Id.*

On March 2, 2001, petitioner saw Dr. Asbury, complaining that people did not seem to be taking her seriously. She wanted to move to West Palm Beach, FL. Med. recs. at Ex. 9, p. 200.

On March 12, 2001, petitioner had an MRI of the brain with and without gadolinium. Med. recs. at Ex. 9, p. 205. This was done in West Palm Beach, FL. The impression was non-specific white matter changes appreciated on FLAIR images without abnormal enhancement, no abnormality of the orbits, and a benign nasopharynx lesion. The optic nerves were not enhanced and there was no abnormal signal seen. *Id.*

On March 14, 2001, petitioner saw Dr. Louis J. Butera, a neurologist in West Palm Beach, FL. Med. recs at Ex. 18, p. 1. Petitioner told Dr. Butera about all the symptoms she had had after her hepatitis B vaccinations. She claimed she had had optic neuritis six months earlier. For a year, she had been on Copaxone and gamma globulin injections weekly, but not on IVIG. *Id.* On examination, a Lhermitte's sign was not present. Med. recs. at Ex. 18, p. 2. She had normal tone and 5/5 power other than 4-4+ weakness of the left hip flexor. Straight leg raising did not induce significant back pain. *Id.* Dr. Butera diagnosed post-vaccinal postimmune demyelinating disorder. Med. recs. at Ex. 18, p. 3.

On May 10, 2001, petitioner saw Dr. Deneke. Med. recs. at Ex. 9, p. 206. She had a flare of uveitis in the right eye with optic neuritis. *Id.*

On March 27, 2001, petitioner had a biopsy for a basal cell carcinoma on her back. Med. recs. at Ex. 9, p. 212.

On March 29, 2001, petitioner had a stomach biopsy for epigastric pain. Med. recs. at Ex. 10, p. 125. No helicobacter-like organisms were identified. *Id.*

On July 2, 2001, petitioner saw Dr. Gwartney, the otolaryngologist. She said a recent MRI showed a lesion on the left side. Med. recs. at Ex. 9, p. 208. She had a small cyst in the nasopharynx which he opened and suctioned out. It was a little mucous cyst which deflated easily. Dr. Gwartney did not see any other lesions in the larynx or hypopharynx. *Id.*

On July 27, 2001, petitioner saw Dr. Van Asche, the gastroenterologist. Med. recs. at Ex. 19, p. 1. Dr. Waisbren had told her she was likely to develop Crohn's disease. A couple of weeks ago, she developed steady lower abdominal pain associated with bloating, nausea, and vomiting. She was taking an awfully high dose of Celebrex (200 mg.) as well as narcotic pain medications and Paxil. He wondered if some of her gastrointestinal problems were not related to her high doses of Celebrex. She said she had lost five pounds over the last 10-14 days. She continued with profound nausea. She was "a little theatrical to palpation...." *Id.* Dr. Van Asche's assessment was multiple GI complaints, "somewhat out of proportion to physical findings." *Id.*

On July 31, 2001, petitioner had a CT done of her abdomen for abdominal pain. Med. recs. at Ex. 10, p. 129. She had diffuse thickening of the wall of a segment of the descending colon, raising the possibility of colitis or diverticulitis. She had a 4 cm. ovarian cyst on the left, and a tiny cyst of the liver. Med. recs. at Ex. 10, p. 130.

On August 2, 2001, petitioner had an esophagogastric duodenoscopy (EGD) performed because of nausea, vomiting, and some dark, tarry stools. Med. recs. at Ex. 10, p. 139. There were two small gastric polyps. Otherwise, it was a normal examination. *Id.*

On August 2, 2001, petitioner had a colonoscopy. Med. recs. at Ex. 10, p. 140. She had possible mild nonspecific colitis but otherwise a normal colonoscopy. *Id.*

On August 14, 2001, petitioner saw Dr. Van Asche, the gastroenterologist. Med. recs. at Ex. 19, p. 2. She continued to have epigastric pain that worsened when she lay down. "Her work-up has been totally negative yet she continues to have rather bitter symptoms." *Id.* She had tried Reglan which did not help and proton pump inhibitors and they did not help. "Nothing seems to help." *Id.* That day, for some reason, she felt fairly well. *Id.*

On August 24, 2001, petitioner had a cervical spine MRI for neck and left arm pain. Med. recs. at Ex. 10, p. 147. She had borderline canal stenosis at C4-5 and C5-6 levels. At C4-5, this was related to a moderate left posterolateral disk protrusion with some associated spur. She had broad posterior disk bulging and associated spur at C5-6. *Id.*

On January 10, 2002, petitioner saw Dr. Asbury to attempt to wean herself from Paxil. Med. recs. at Ex. 9, p. 220. She felt like she had been taking Paxil for a long time and, occasionally, when she missed a dose, she had nausea, vomiting, and feeling bad. *Id.*

On March 11, 2002, petitioner saw Dr. Asbury with a history of having a diaphoretic spell with palpitations in the dentist chair. Med. recs. at Ex. 9, p. 221.

On April 5, 2002, petitioner saw Dr. Deneke. She was working out with a trainer and feeling better. Her motion improved. She was moving to West Palm Beach to be closer to a neurologist and consider IVIG. Med. recs. at Ex. 9, p. 224.

On May 13, 2002, petitioner had a ventilation perfusion lung scan because of shortness of breath. Med. recs. at Ex. 10, p. 155. She had no acute cardiopulmonary disease. There was slight scoliosis in the thoracic spine. It was a normal scan otherwise. *Id.*

On June 11, 2002, Dr. Waisbren's test results showed petitioner still positive for cytomegalovirus, Epstein Bar virus IgG, and herpes II. Med. recs. at Ex. 16, p. 36. Her triglycerides were 239. *Id.*

On June 27, 2002, Dr. Waisbren wrote petitioner a letter suggesting that she contact another patient whose husband won her workmen's compensation case after hepatitis B reaction, and suggested that petitioner's attorney contact this man. Med. recs. at Ex. 16, p. 43.

On July 18, 2002, petitioner saw Dr. Ira G. Warshaw, a family practice physician in North Pam Beach, FL. Med. recs. at Ex. 22, p. 1. She gave him a history of medical problems stemming from her first hepatitis B vaccination. Her inflammatory demyelinating process was not felt to be MS. *Id.*

On July 26, 2002, petitioner saw Dr. Butera, the neurologist. Med. recs. at Ex. 18, p. 4. Petitioner had a burning sensation involving her left forehead radiating into her cheek with an occasional twitch. On examination, her eye disks were unremarkable. She had no Lhermitte's sign. There was no facial weakness. Power was 5/5 with normal tone. Sensory testing was intact to pin and vibration. Limb coordination was unremarkable as was gait. Reflexes were symmetrical, 2 in the arms, 3 at the knees, 1/4 at the ankles. He diagnosed post-vaccinal demyelinating disorder secondary to hepatitis B vaccination. *Id.*

On July 29, 2002, petitioner had an MRI of the brain with and without magnevist enhancement. Med. recs. at Ex. 18, p. 5. There was scattered white matter disease in both hemispheres suggesting a demyelinating process. *Id.*

On August 2, 2002, Dr. Waisbren wrote a letter to petitioner's new doctor, Dr. Butera, in West Palm Beach, FL, stating that petitioner had never been significantly sick prior to hepatitis B

vaccination and that she had a progressive acquired autoimmune disease since 1993. He suggested that Dr. Butera might be interested in reading Dr. Waisbren's book[11] on hepatitis B vaccine toxicity. Med. recs. at Ex. 16, p. 44.

On August 22, 2002, petitioner returned to Dr. Warshaw, having received a gamma globulin injection. Med. recs. at Ex. 22, p. 2.

On September 4, 2002, petitioner returned to Dr. Warshaw for another gamma globulin injection. *Id.* She had gone to the University of Miami where it was felt she would benefit from intravenous immunoglobulin. *Id.*

On September 11, 2002, petitioner saw Dr. William A. Sheremata, a Professor of Neurology at the University of Miami. Med. recs. at Ex. 23, p. 1. From petitioner's description of her symptoms following hepatitis B vaccinations, Dr. Sheremata thought she had post-vaccinal encephalomyelitis although her MRIs were normal. *Id.* Petitioner had used a variety of potent analgesics including Oxycontin, Duragesic patches, and more recently Methadone. The use of those drugs might have contributed to her memory loss. Med. recs. at Ex. 23, p. 3. Petitioner stated she trembled, but this was not confirmed on examination. She was remarkably inattentive and had difficulty responding to the simplest questions. The optic discs were probably normal. She had prominent loss of smooth visual pursuit on horizontal gaze. Surprisingly, she could carry out tandem gait with only minimal difficulty but Romberg testing was prominently abnormal. Her gait was prominently spastic and she had hyperreflexia of the lower extremities with clonic knee jerks and increased ankle jerks. Bilateral Babinski reflexes

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[11] "The hepatitis B vaccination program in the United States–lessons for the future" by Burton A. Waisbren, published in 2002, available from Charles Street Bookshop in Massachusetts for $35.00 plus shipping (see www.amazon.com).

were present. *Id.* Confounding her problems was her drug dependence. She had developed secondary-progressive MS. Methotrexate manages large granular lymphocytes described in her peripheral smear, but Methotrexate is associated with multiple autoimmune phenomena. Med. recs. at Ex. 23, p. 4.

On October 1, 2002, petitioner saw Dr. Richard J. Stropp, a pain management expert. Med. recs. at Ex. 24, p. 1. Petitioner told Dr. Stropp of post-vaccinal problems. She had a new onset of severe pain in her left leg since July 5, 2002. *Id.* There was burning in her legs and feet in a non-dermatomal distribution. Med. recs. at Ex. 24, p. 2. Petitioner told Dr. Stropp that she had had seizures with the onset of this syndrome and neuropathy. *Id.* She had been on Methotrexate for 13 months. *Id.* On examination, petitioner had full range of motion in all four extremities. Med. recs. at Ex. 24, p. 3. Petitioner appeared to have a left S1 radiculopathy. Dr. Stropp prescribed Methadone. Med. recs. at Ex. 24, p. 4.

On November 14, 2002, petitioner returned to Dr. Stropp. Med. recs. at Ex. 24, p. 5. An MRI of the lumbar spine on September 19, 2002 was normal. His assessment was mechanical back pain and left S1 radiculopathy, resolving on chronic narcotic medication. *Id.*

On November 14, 2002, petitioner saw Dr. Mark R. Stein, an allergist. Med. recs. at Ex. 25, p. 1. Petitioner told him she had seizures, fever, optic neuritis, uveitis, and positive reactive antibodies after receiving hepatitis B vaccine. She told him she had an autoimmune demyelinating neuropathy. *Id.* His initial impression was possible demyelinating neuropathy of uncertain etiology with no clearcut immunologic data suggesting to him an absolute etiology (having reviewed Dr. Burton Waisbren's test results). Med. recs. at Ex. 25, p. 2.

On November 22, 2002, petitioner returned to Dr. Warshaw, complaining of decreasing vision in her left eye associated with pain. Med. recs. at Ex. 22, p. .3. Several years ago, she had the same symptoms in her right eye which she said progressed from iritis to optic neuritis. Dr. Warshaw wondered if she had iritis. *Id.*

On November 22, 2002, petitioner saw Dr. George C. Wong, an ophthalmologist. Med. recs. at Ex. 26, p. 1. She developed discomfort in the left eye the night before, and the eye became red, blurry, and photophobic that day. She had a similar episode in the right eye two years before which progressed very rapidly to significant loss of vision. On examination, petitioner had significant iritis in the left eye. On dilated funduscopic examination, the optic discs were sharp with no evidence of edema. The vitreous was clear with no evidence of cells or inflammation posteriorly. *Id.*

On November 23, 2002, petitioner went to Anne Bates Leach Eye Hospital, Bascom Palmer Eye Institute, for an Emergency Ocular Evaluation. Med. recs. at Ex. 27, p. 1. She complained of pain in the left eye and decreased visual acuity. The onset was one day before. *Id.* The impression was anterior uveitis of the left eye. Med. recs. at Ex. 27, p. 2.

On November 25, 2002, petitioner had an Ocular Evaluation at Bascom. Med. recs. at Ex. 27, p. 3. Dr. Sheremata had mentioned large granular lymphocytes on peripheral smear. *Id.*

On November 26, 2002, Dr. Waisbren wrote a letter to attorney Altom Maglio, stating that the "government and all attorneys she has seen have stone walled her attempt to get workmen's compensation...." Med. recs. at Ex. 16, p. 45. He encouraged Mr. Maglio with his last sentence: "C'mon, let's take on Uncle Sam." *Id.*

On December 3, 2002, petitioner had an MRI of her orbits with and without contrast. Med. recs. at Ex. 27, p. 5. The impression was nonspecific multifocal white matter disease. None of the multiple tiny foci of high FLAIR signal scattered throughout the white matter showed enhancement on post-gadolinium sequences. The differential included infectious causes as well as demyelinating causes such as MS. She had questionable enhancement in the left optic nerve. The differential could include a small venous structure. She had a small pineal cyst which was to the right of the midline involving the proximal left optic nerve. *Id.*

On December 4, 2002, petitioner may have had an electroretinogram (ERG) performed. The confusion stems from the report by Dr. Byron L. Lam stating the ERG was done on Mona Diamond, but Nicolette Davis' name is at the top of the report. Med. recs. at Ex. 27, p. 6. The right eye was markedly reduced in amplitude centrally. The left eye was mildly reduced in amplitude centrally. The full-field ERG responses were within the normal range but showed significant asymmetry. The findings indicated retinal dysfunction in the left eye especially centrally with the right eye demonstrating some decrease in central responses. *Id.* Dr. Lam ascribed the probable retinal damage due to a previous uveitis which took months to be controlled. Med. recs. at Ex. 27, p. 8.

On December 11, 2002, petitioner saw Dr. Warshaw. She continued to have significant vision loss in her left eye related to uveitis which did not respond to intravenous steroids. Med. recs. at Ex. 22, p. 4.

On December 13, 2002, Dr. Warshaw wrote a "To Whom It May Concern" letter, pleading for approval for petitioner to have IVIG infusion. Med. recs. at Ex. 22, p. 5.

On January 13, 2003, petitioner saw Dr. Stropp. She stated she missed her December office visit because of blindness from her autoimmune disease. She claimed she was falling about three times a week due to left leg pain. Med. recs. at Ex. 24, p. 6.

On January 16, 2003, petitioner returned to Bascom Palmer Eye Institute, saying that up until that week, she had been unable to see and used a magnifier to read. The prior Sunday, she got throbbing pain. Yesterday morning, she could see. Med. recs. at Ex. 27, p. 12.

On February 10, 2003, petitioner saw Dr. Stropp, stating she had pain in her back radiating into the left buttock and left posterior thigh down past the left knee. She spent a lot of time discussing the vision in her eye and her generalized autoimmune dysfunction. On physical examination, her back was essentially negative. Med. recs. at Ex. 24, p. 7.

On March 10, 2003, petitioner saw Dr. Stropp, stating she had pain in her low back radiating into the left buttock and pain in the left lateral calf and toes with numbness. She complained of numbness in a non-dermatomal distribution going from above the bilateral malleoli to above the knee. Of note, her September 19, 2002 lumbar spine MRI was negative. She spent time discussing her probable disease. Her physical examination was essentially negative. Med. recs. at Ex. 24, p. 8.

On April 9, 2003, petitioner saw Dr. Stropp, stating her legs felt better, but complaining of vertigo with tinnitus in the left ear. Her physical examination was negative. Med. recs. at Ex. 24, p. 9.

On April 18, 2003, petitioner saw Dr. Warshaw, complaining of dysuria, control difficulties, and hair loss. She still had not received approval for IVIG. Her memory was intermittently poor. Med. recs. at Ex. 22, p. 6.

On April 21, 2003, a note in Dr. Warshaw's records states that all petitioner's labs were within normal. *Id.* Petitioner telephoned that she had severe fatigue, anxiety, and depression. She asked for a counselor or psychologist. Dr. Aradi, a psychologist, and Dr. Ramoanov, a psychiatrist, were recommended to her on May 27, 2003. *Id.*

On May 12, 2003, petitioner saw Dr. Stropp, complaining that her legs were slightly more painful that month. Her physical examination was negative other than a slight left antalgic leg drag. Med. recs. at Ex. 24, p. 10.

On June 9, 2003, petitioner saw Dr. Stropp, saying that Keppra reduced the burning electric shock pains she had in her leg. Her physical examination was negative except for a balance disorder with difficult gait. Med. recs. at Ex. 24, p. 11.

On June 18, 2003, petitioner saw Dr. Stropp, describing painful numbness in her left lower leg. There appeared to be a slight decrease in calf diameter on the left versus the right. Her gait was antalgic dragging the left leg. Med. recs. at Ex. 24, p. 12.

On June 24, 2003, Dr. Waisbren tested petitioner and she was positive for Epstein Barr virus IgG. Med. recs. at Ex. 16, p. 46. She had high triglycerides of 252. Med. recs. at Ex. 16, p. 48. In an undated form letter to petitioner, he states that the tests are consistent with the hypothesis that hepatitis B vaccine plus cytomegalovirus and Epstein Barr virus merged to form an antigen that evoked anti-myelin T cells that attacked petitioner's nervous system, causing multiple sclerosis. He put petitioner on Depakote. He concludes that his specialty of autoimmunity is starting to get recognized although he was not the only one who practiced it. Med. recs. at Ex. 16, p. 51.

DISCUSSION

This is a causation in fact case. To satisfy her burden of proving causation in fact, petitioner must offer "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Secretary of HHS, 418 F. 3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

> A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" the logical sequence being supported by "reputable medical or scientific explanation[,]" *i.e.*, "evidence in the form of scientific studies or expert medical testimony[.]"

In Capizzano v. Secretary of HHS, 440 F.3d 1274, 1325 (Fed. Cir. 2006), the Federal Circuit said "we conclude that requiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen...."

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, at 1149. Mere temporal association is not sufficient to prove causation in fact. Hasler v. US, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must show not only that but for the vaccine, she would not have had reactive arthritis and MS, but also that the vaccine was a substantial factor in bringing about reactive arthritis and MS. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

There are a number of problems in this case. First, petitioner never saw a physician to complain of post-vaccinal symptoms until November 1999, five and six years later. This was after she had spoken to Bonnie Dunbar and received the idea that she might be able to blame all her symptoms on hepatitis B vaccine. But all of petitioner's visits to doctors in the time periods when she received hepatitis B vaccine do not reflect any vaccine injuries that she now asserts in her affidavit or in the histories to Dr. Waisbren, Dr. Butera, and other doctors.

After her first hepatitis B vaccination, her first medical visit a month later was for nipple discharge and a spot on her stomach. She did not see any physician between her second and third hepatitis B vaccinations. Two and one-half months after her third vaccination, she saw a physician to report ear popping, something that had bothered her since February 1994, a month before the third vaccination. All the symptoms she claims in her affidavit and which she gave in histories to Dr. Waisbren, Dr. Butera and others which supposedly occurred after the third vaccination actually occurred years later.

In January 1999, petitioner talked with Bonnie Dunbar and learned about hepatitis B vaccine and autoimmune disease. She filed her petition to receive compensation in the Vaccine Program on July 26, 1999. She first saw Dr. Waisbren on November 1, 1999 with the new version of her medical history. She first saw Dr. Butera on March 14, 2001, repeating this new history.

Well-established case law holds that information in contemporary medical records is more believable than that produced years later at trial. United States v. United States Gypsum Co., 333 U.S. 364, 396 (1948); Burns v. Secretary, HHS, 3 F.3d 415 (Fed. Cir. 1993); Ware v. Secretary, HHS, 28 Fed. Cl. 716, 719 (1993); Estate of Arrowood v. Secretary, HHS, 28 Fed. Cl.

453 (1993); Murphy v. Secretary, HHS, 23 Cl. Ct. 726, 733 (1991), aff'd, 968 F.2d 1226 (Fed. Cir.), cert. denied sub nom. Murphy v. Sullivan, 113 S. Ct. 263 (1992); Montgomery Coca-Cola Bottling Co. v. United States, 615 F.2d 1318, 1328 (1980). Contemporaneous medical records are considered trustworthy because they contain information necessary to make diagnoses and determine appropriate treatment:

> Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Cucuras v. Secretary, HHS, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Thirdly, petitioner's MS (if indeed she has MS) had its onset in 1999. Her October 7, 1999 MRI, which showed areas of white matter hyperintensities, was markedly different than her January 18, 1999 MRI which did not show such areas. Petitioner will have difficulty proving that hepatitis B vaccine causes MS whose onset is five and six years after vaccination.

In Werderitsh v. Secretary of HHS, No. 99-319V, 2006 WL 1672884 (Fed. Cl. Spec. Mstr. May 26, 2006), the undersigned ruled that hepatitis B vaccine can cause MS and did so in that case. However, the onset interval after vaccination in Werderitsh was one month. Respondent's expert, Dr. Roland Martin, testified in the Omnibus hepatitis B vaccine-demyelinating diseases proceeding that the appropriate onset interval, if a vaccination were to cause an acute demyelinating reaction, would be a few days to three to four weeks. Stevens v. Secretary of HHS, No. 99-594V, 2006 WL 659525, at *15 (Fed. Cl. Spec. Mstr. Feb. 24, 2006). Petitioners' expert Dr. Vera Byers testified that onset would be four days to four weeks. Stevens tr. at 97, 102. Five or six years post-vaccination is not three days to four weeks.

Fourthly, there is no proof that hepatitis B vaccine causes spondyloarthopathy or ankylosing spondylitis whose onset is years later.

Fifthly, petitioner's history of sexual assault dates to October 1995 and petitioner has consistently given a history of problems dating back to that time period and even from 1989 when she suffered sexual harassment at the U.S. Marshals academy. Work stress and post-traumatic stress syndrome are not vaccine reactions. On numerous occasions, she has told doctors that she was vibrantly healthy before 1995 and 1996.

Sixthly, the diagnoses of the internist Dr. Waisbren and the neurologist Dr. Butera (as well as all the other doctors to whom she told histories of post-vaccinal symptoms) rely solely upon the accuracy of petitioner's description to them of neurologic symptoms after the hepatitis B vaccinations. But her history was not based on the actual medical facts of her life, as a perusal of her extensive medical history shows. Since these doctors' diagnoses of post-vaccinal demyelinating disorder secondary to hepatitis B vaccination are only as valid as the facts upon which they relied in reaching those diagnoses, and those facts are false, their diagnoses have no credibility. By 2002, she was giving a history to Dr. Stropp and Dr. Stein that she had seizures after hepatitis B vaccination. There is no medical record of petitioner having seizures after hepatitis B vaccination or at any time.

Petitioner's change in her histories five and six years after the vaccinations does not bode well for petitioner's proving a prima facie case of causation in fact. The undersigned doubts that petitioner will be able to obtain an expert who, if the expert reads all of petitioner's histories, will be supportive of petitioner's allegations.

Petitioner is ORDERED TO SHOW CAUSE why this case should not be dismissed by **April 27, 2007**. If petitioner intends to proceed, petitioner shall file all medical records from 1989 to 1993.

IT IS SO ORDERED.

DATE

Laura D. Millman
Special Master